

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of vitamin B12 supplementation on levels of fatigue, depression, anxiety and stress hemodialysis patients

#### Protocol summary

##### Summary

The aim of this study was to determine the effect of vitamin B12 supplementation on fatigue, depression, anxiety and stress in hemodialysis patients. High plasma concentrations of total homocysteine was considered as a criterion. Study was on hemodialysis patients from selected hospitals No.1 and No.2. The sample size was 86 patients involved intravenous injection of ml/mcg 100 Vitamin B12 after dialysis process, which was carried out three times a week for two months and then by the end of the intervention, to assess the durability of vitamin B12, there was no intervention for a month(washout). 21-item questionnaire measure of depression, anxiety, stress and multidimensional questionnaire measuring fatigue at the beginning and end of each month of study was completed by participants. At the beginning of Intervention, at the end of the second month of intervention and end of washout, laboratory studies were conducted.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012122611892N1**

Registration date: **2013-01-28, 1391/11/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-01-28, 1391/11/09

##### Registrant information

##### Name

Samira Savari

##### Name of organization / entity

Faculty of Nursing of Baqiyatallah University of

Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7710 3725

##### Email address

rnehrr1739@bmsu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Nephrology and Urology Research center Faculty of Nursing of Baqiyatallah University of Medical Science.  
Responsible person: Dr Behzad Eynollahi

##### Expected recruitment start date

2011-12-21, 1390/09/30

##### Expected recruitment end date

2012-03-19, 1390/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of vitamin B12 supplementation on levels of fatigue, depression, anxiety and stress hemodialysis patients

##### Public title

Effect of vitamin B12 on reducing fatigue, depression, anxiety and stress in hemodialysis patients

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

inclusion criteria: a minimum of 18 years; a minimum literacy; a least 3 months have passed since the first dose of hemodialysis; a high concentration of plasma total homocysteine exclusion criteria: people who did research during strenuous crisis(acute illness,

hospitalization, surgery extended) or emotional (grief, divorce)they are excluded

#### Age

From **18 years** old to **80 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **86**

#### Randomization (investigator's opinion)

N/A

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Single

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Baqiyatallah University of Medical Sciences

##### Street address

Molla sadra Ave,Vanak

##### City

Tehran

##### Postal code

##### Approval date

2011-11-29, 1390/09/08

##### Ethics committee reference number

28

## Health conditions studied

### 1

#### Description of health condition studied

hemodialysis

#### ICD-10 code

Z49.0

#### ICD-10 code description

Preparatory care for dialysis

## Primary outcomes

### 1

#### Description

Fatigue

#### Timepoint

Befor Intervention, one and two months after intervention, One month after the end of intervention

#### Method of measurement

MFI

## Secondary outcomes

### 1

#### Description

Total homocysteine plasma

#### Timepoint

Befor intervention, two months after the intervention, one month after the end of intervention

#### Method of measurement

laboratory tests

## Intervention groups

### 1

#### Description

Infusion intravenous vitamin B12 two months in the end of hemodialysis procccece

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Baqiatallah, Chamran Hospitals

##### Full name of responsible person

Samira Savari

##### Street address

Room 408, Fourth Floor, Block 16, Provincial Park, Martyr Babaei Highway

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Nephrology and Urology Research center Baqiyatallah University of Medical Sciences

##### Full name of responsible person

Dr. Behzad Eynollahi

##### Street address

Molla Sadra Ave, Vanak

##### City

Tehran

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor

**organization/entity?**

Yes

**Title of funding source**

Nephrology and Urology Research center Baqiyatallah University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

**Person responsible for general inquiries****Contact****Name of organization / entity**

Faculty of Nursing of Baqiyatallah University of Medical Sciences

**Full name of responsible person**

Samira Savari

**Position**

MSc

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**Full name of responsible person**

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Master of Nursing Education

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**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*